

## **REMARKS**

Applicants respectfully request consideration of the foregoing amendments and the following reasons upon continued examination of the present application on the merits.

### **I.      Status of the Claims**

Claim 30 has been amended with exemplary support in the specification, e.g., at page 24, Example 1. Claims 1, 30 and 35 have been amended to incorporate several recitations of claims 37, 41, 45 and 49, which have been cancelled accordingly.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 will be pending.

### **II.     Rejection of Claims under 35 U.S.C. §102(a)**

Claims 1, 2, 4-11, 13-22, 25-38, 41-43, 45, 46, 49, 50 and 53 remain rejected under 35 U.S.C. §102(a) for alleged anticipation by PCT Publication No. WO 99/02665 by Liversidge et al. (“Liversidge”). Applicants respectfully traverse the rejection.

The claimed invention is directed to a solid dose controlled release nanoparticulate composition comprising: (a) a drug having an effective average particle size of less than about 1000 nm, (b) at least one surface stabilizer associated with the surface of the drug particles, and (c) at least one pharmaceutically acceptable high molecular weight rate-controlling polymer which is integrated in a rate-controlling matrix with the drug or which coats the drug.

**A. There is no evidence on the record to support the Examiner's rejection rationale.**

The Examiner asserts that Liversidge anticipates the claimed invention because "Liversidge teaches the use of the same method to obtain the claimed nanoparticles." Advisory Action, page 2, 3<sup>rd</sup> paragraph.

First, the claimed invention relates to a controlled release formulation which comprises a rate-controlling matrix formed by a high molecular weight rate-controlling polymer. The anticipation rejection lacks support because Liversidge fails to meet the structural limitation of a rate-controlling matrix formed by a high molecular weight rate-controlling polymer.

Second, the Examiner asserts that Liversidge's process is "identical or substantially identical" to the process of the claimed invention. *Id.* This assertion is incorrect. As discussed in prior responses, Liversidge does not teach or suggest a controlled-release formulation. Not surprisingly, Liversidge's process does not include a step to select the formulation which has the desired release profile. Therefore, there is no evidence that the prior-art process is identical to the process of the claimed invention.

**B. The cellulosic surface stabilizer of Liversidge does not teach or suggest Applicants' claimed rate controlling polymer**

The Examiner contends that Liversidge's use of at least two surface stabilizers, one being a cellulosic surface stabilizer, meet Applicants' claim limitations of the surface stabilizer and the high molecular weight rate controlling polymer. *Id.*, page 3, 1<sup>st</sup> full paragraph. However, the Examiner is silent as to Applicants' prior argument that Liversidge fails to meet the structural limitation of Applicants' claim which would require that the cellulosic surface stabilizer is integrated into a matrix or coats the HIV drug particles to control the release rate of the drug.

Accordingly, Liversidge fails to teach each and every aspect to anticipate the claimed invention.

**III. Rejection of Claims under 35 U.S.C. §103(a)**

Claims 1, 4-10, 12-18, 21, 22, 25, 26, 30, 32-35 and 37-54 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 4,665,081 to Doi et al. (“Doi”) in view of U.S. Patent No. 4,765,990 to Sugimoto et al. (“Sugimoto”). Applicants respectfully traverse the rejection.

As previously submitted, neither Doi nor Sugimoto discloses a nanoparticulate active agent composition comprising a surface stabilizer associated with the surface of the active agent particles. Moreover, a surface stabilizer to prevent the particles of the active agent from agglomeration or aggregation is not required for either Doi’s or Sugimoto’s composition because the particle size of these prior-art compositions are large enough to maintain the stability of the composition such that the addition of a stabilizing agent is not needed..

The Examiner asserts that the feature that Applicants rely on, i.e., a surface stabilizer to prevent the particles of the active agent from agglomeration or aggregation, is not recited in the rejected claims. *Id.*, the paragraph bridging pages 3 and 4. Applicants respectfully disagree.

The pending claims require the presence of a surface stabilizer and that the surface stabilizer be adsorbed on the surface of the active agent particles. Neither the ingredient requirement nor the structural requirement is met by the combined teachings of the cited art.

Furthermore, Doi teaches *away* from the claimed invention by recommending against substituting the ingredient, such as casein. The Examiner states that casein is one of the surface stabilizers of the claimed invention. Without acquiescing to the stated basis for the rejection, Applicants choose to expedite the prosecuting by submitting the claim amendments, which do not include casein as a surface stabilizer.

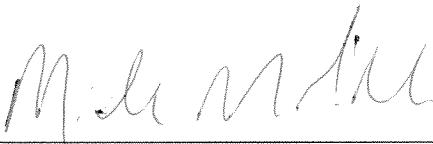
Accordingly, withdrawal of the rejection is respectfully requested.

## CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By 

Date: July 19, 2010

FOLEY & LARDNER LLP  
Customer Number: 31049  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Attorney for Applicant  
Registration No. 34,717